CMR: Implanted device safety

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Today, the presence of a cardiac pacemaker (PM) or an implantable cardioverter/defibrillator (ICD) is still considered an absolute contraindication to magnetic resonance imaging (MRI) by most institutions, and most patients with these devices are excluded from having MRI. A previous study has shown that MRI is indicated in 17% of all patients with pacemakers within 12 months after device placement \(^1\), which demonstrates the need for a practical, safe approach for performing MRI on pacemaker or ICDs patients.

Potential risks associated with MRI of patients with PMs and ICDs are related to the possible interactions of the devices with the static magnetic field and pulsed fields of the MRI system:

1. **Force and Torque on PMs/ICDs**
   - Translational forces and torque on PM/ICD devices and leads have been evaluated in several studies and have been shown to be small enough (less than the gravity) not to represent a safety concern at 0.5T and 1.5T for modern PM/ICDs, which only contain minimal amounts of ferromagnetic materials \(^2,3\).

2. **Influence on device function and unintended PM reprogramming**
   - Changes in device function are frequently observed when PM enter the static magnetic field. Despite earlier assumptions that the reed switch of a PM/ICD will always close in a strong magnetic field, it has been shown that is does so in only \(\approx 50\%\) of the cases \(^4\). This has major implications for the patient, as closure of the reed switch - in PM patients - usually leads to asynchronous pacing and – in ICD patients - to inhibition of shock delivery. Additionally, unintended reprogramming of the device may occur due to an electrical reset, which represents a safety mode with backup parameters, in PMs usually an inhibited pacing mode (such as VVI 65), whereas in ICDs therapy delivery will be activated. Subsequently, inhibition of PM output due to oversensing EM noise as the patient’s intrinsic rhythm may be fatal if the patient is PM dependant.

3. **Gradient fields**
   - The time varying gradient fields can potentially induce voltages of about 420 mV in the lead \(^5\). These induced voltages within the PM/ICD leads can potentially lead to direct stimulation of the heart. To minimize this risk, the PM should be reprogrammed to bipolar pacing. Furthermore, these induced voltages can mimic intrinsic cardiac activity and thus lead either to output inhibition (PMs) or to arrhythmia detection with subsequent attempt to therapy delivery (ICDs). However, it is uncertain if -within the MRI environment- ICDs are able to charge the capacitor, which is necessary for therapy delivery.

4. **Radiofrequency fields**
   - Substantial heating of PM/ICD leads has been demonstrated in-vitro (20.4 to 88.8 °C) \(^6,9\). There is evidence that myocardial tissue alterations can occur during MRI of PM patients: Significant changes of the pacing capture thresholds and elevations in serum troponin as a marker for myocardial damage have been observed in-vivo, as well a loss of capture for 12 hours. Heating itself is caused by an EM resonance effect between the RF field and the PM lead, therefore the wavelength of the RF fields and the size of the object are important. Other factors contributing to RF-related heating are SAR values, duty cycle, active scanning time, configuration of the object (closed loop?), coverage of the object by the RF field, and ferromagnetic characteristics of the object.

These risks have been evaluated in several in-vitro and in-vivo studies \(^7,8,10-12\). Various different strategies have been used so far to minimize the RF-related heating of the PM electrodes (limiting SAR, limiting active scanning time, exclusion of the thoracic region) and to minimize the interference with PM/ICD function (reprogramming of PM to an asynchronous or sense-only mode, deactivating the therapy function in ICDs). In none of the three major clinical trials with a total of 245 MRI exams, any clinically relevant complication has occurred \(^10-12\). Most experts agree, that MRI on PM patients may be performed with a reasonable risk/benefit ratio if appropriate precautionary measures are taken: 1. limiting extent and duration of RF-exposure to minimize RF-related heating 2. reprogramming of PM/ICD to minimize interference of MR fields with device function 3. continuous vital sign monitoring using ECG and pulse oximetry, 4. performing MR procedures on PM/ICDs patients only with an electrophysiologist present and with full resuscitation facilities available.

New MR conditional pacemaker models are now available, which have been designed and tested to be used in the MR environment under specific conditions.


